

IN THE CLAIMS

Applicant has submitted a new complete claim set showing marked up claims with insertions indicated by underlining and deletions indicated by strikeouts and/or double bracketing.

1-32. (Canceled)

33. (Currently Amended) A method of increasing localized bloodflow in tissue by delivering to skin a substance that is a nitric oxide precursor selected from the group consisting of L-arginine and L-arginine derivatives, the method comprising the step of:

applying topically to the skin a delivery vehicle for the substance, said delivery vehicle comprising an amount of the substance effective to increase localized tissue bloodflow when combined with an agent for creating a hostile biophysical environment comprising an ionic salt mixture comprising choline chloride, sodium chloride, and magnesium chloride, the agent being at a concentration sufficient to create the hostile biophysical environment, the hostile biophysical environment causing the substance to migrate from the delivery vehicle to the skin where the substance is absorbed by tissue in the area surrounding the skin where the substance is applied.

34. (Currently Amended) The method of claim 33 wherein the delivery vehicle is selected from the group consisting of topical creams, topical liquids, topical lotions, and topical ointments, ~~the delivery vehicle further comprising~~ wherein an the ionic salt mixture comprising comprises, by weight, sodium chloride (0.25% to 25%), choline chloride (0.25% to 25%), and magnesium chloride (0.25% to 25%).

35. (Currently Amended) The method of claim 33 wherein the delivery vehicle is a hydrophobic delivery vehicle comprising the substance and ~~an the ionic salt mixture, the ionic salt mixture~~ comprising, by weight, sodium chloride (0.25% to 25%), choline chloride (0.25% to 25%), and magnesium chloride (0.25% to 25%).

36-37. (Canceled)

38. (Previously Presented) The method of claim 33 wherein the act of applying comprises applying a transdermal patch comprising the substance and a penetrating agent to the skin.

39. (Previously Presented) A method of delivering to skin a nitric oxide releasing substance selected from the group consisting of L-arginine, L-arginine salts, and L-arginine derivatives, the method comprising the step of:

applying topically to the skin a delivery vehicle for the substance, said delivery vehicle comprising the substance and an ionic salt at a concentration sufficient to create a hostile biophysical environment, the hostile biophysical environment causing the substance to migrate from the delivery vehicle to the skin where the substance is absorbed by tissue,

wherein said delivery vehicle comprises, by weight, water (20%-80%), mineral oil (3%-18%), glyceryl stearate (0.5%-12%), squalene (0.2%-12%), cetyl alcohol (0.1%-11%), propylene glycol stearate (0.1%-11%), wheat germ oil (0.1%-6%), glyceryl stearate (0.1%-6%), isopropyl myristate (0.1%-6%), stearyl stearate (0.1%-6%), polysorbate 60 (0.1%-5%), propylene glycol (0.05%-5%), tocopherol acetate (0.05%-5%), collagen (0.05%-5%), sorbitan stearate (0.05%-5%), vitamin A&D (0.02%-4%), triethanolamine (0.01%-4%), methylparaben (0.01%-4%), aloe vera extract (0.01%-4%), imidazolidinyl urea (0.01%-4%), propylparaben (0.01%-4%), bha (0.01%-4%), L-arginine hydrochloride (0.25% to 25%), sodium chloride (0.25% to 25%), and magnesium chloride (0.25% to 25%).

40. (Previously Presented) The method of claim 39 wherein the delivery vehicle further comprises choline chloride (0.25%-25% by weight).

41. (Previously Presented) The method of claim 39 wherein the delivery vehicle further comprises L-arginine glutamate (0.25%-25% by weight).

42. (Previously Presented) A method of treating impotence in a male comprising:
delivering to a penis a substance that is a nitric oxide precursor selected from the group consisting of L-arginine and L-arginine derivatives by topically applying to the penis a delivery vehicle for the substance, said delivery vehicle comprising an amount of the substance effective to increase bloodflow in the penis when combined with an agent for creating a hostile biophysical environment at a concentration sufficient to create the hostile biophysical environment, the hostile biophysical environment causing the substance to migrate from the delivery vehicle to the penis where the substance is absorbed by the penis.
43. (Previously Presented) The method of claim 42 wherein the delivery vehicle is selected from the group consisting of topical creams, topical liquids, topical lotions, and topical ointments, the substance is L-arginine hydrochloride, 0.25% to 25% by weight, the delivery vehicle further comprising an ionic salt mixture comprising choline chloride at 10% by weight, sodium chloride at 10% by weight, and magnesium chloride at 5% by weight.
44. (Previously Presented) The method of claim 42 wherein the delivery vehicle is a hydrophobic delivery vehicle comprising the substance, wherein the substance is L-arginine hydrochloride at 12.5% by weight, and wherein the delivery vehicle further comprises an ionic salt mixture comprising choline chloride at 10% by weight, sodium chloride at 10% by weight and magnesium chloride at 5% by weight.
- 45-46. (Canceled)
47. (Previously Presented) A method of treating impotence in a male by delivering to skin a nitric oxide releasing substance selected from the group consisting of L-arginine, L-arginine salts, and L-arginine derivatives, the method comprising the step of:
applying topically to a penis a delivery vehicle for the substance, said delivery vehicle comprising the substance and an ionic salt at a concentration sufficient to create a hostile biophysical environment, the hostile biophysical environment causing the substance

to migrate from the vehicle to the penis where the substance is absorbed by tissue,

wherein said delivery vehicle comprises, by weight, water (20%-80%), mineral oil (3%-18%), glyceryl stearate (0.5%-12%), squalene (0.2%-12%), cetyl alcohol (0.1%-11%), propylene glycol stearate (0.1%-11%), wheat germ oil (0.1%-6%), glyceryl stearate (0.1%-6%), isopropyl myristate (0.1%-6%), stearyl stearate (0.1%-6%), polysorbate 60 (0.1%-5%), propylene glycol (0.05%-5%), tocopherol acetate (0.05%-5%), collagen (0.05%-5%), sorbitan stearate (0.05%-5%), vitamin A&D (0.02%-4%), triethanolamine (0.01%-4%), methylparaben (0.01%-4%), aloe vera extract (0.01%-4%), imidazolidinyl urea (0.01%-4%), propylparaben (0.01%-4%), bha (0.01%-4%), L-arginine hydrochloride (0.25% to 25%), sodium chloride (0.25% to 25%), and magnesium chloride (0.25% to 25%).

48. (Previously Presented) The method of claim 47 wherein the delivery vehicle further comprises choline chloride (0.25%-25% by weight).
49. (Previously Presented) The method of claim 47 wherein the delivery vehicle further comprises L-arginine glutamate (0.25%-25% by weight).
50. (Previously Presented) The method according to any one of claims 42-49 wherein the delivery vehicle is contained in a condom which is placed on the penis.
51. (Previously Presented) A method of promoting hair growth comprising:
 - delivering, to a selected area of skin where hair growth is desired, a substance that is a nitric oxide precursor selected from the group consisting of L-arginine and L-arginine derivatives, by topically applying, to the selected area of skin where hair growth is desired, a delivery vehicle for the substance, said delivery vehicle comprising an amount of the substance effective to increase localized tissue bloodflow when combined with an agent for creating a hostile biophysical environment at a concentration sufficient to create the hostile biophysical environment, the hostile biophysical environment causing the substance to

migrate from the delivery vehicle, to the selected area of the skin where hair growth is desired, where the substance is absorbed by the selected area of the skin.

52. (Previously Presented) The method of claim 51 wherein the delivery vehicle is selected from the group consisting of topical creams, topical liquids, topical lotions, and topical ointments, the delivery vehicle further comprising an ionic salt mixture comprising, by weight, sodium chloride (0.25% to 25%), choline chloride (0.25% to 25%), and magnesium chloride (0.25% to 25%).

53. (Previously Presented) The method of claim 51 wherein the delivery vehicle is a hydrophobic delivery vehicle comprising the substance, a penetrating agent, and an ionic salt.

54-55. (Canceled)

56. (Previously Presented) A method of promoting hair growth by delivering, to a selected area of skin where hair growth is desired, a nitric oxide releasing substance selected from the group consisting of L-arginine, L-arginine salts, and L-arginine derivatives, the method comprising:

topically applying, to the selected area of the skin where hair growth is desired, a delivery vehicle for the substance, said delivery vehicle comprising the substance and an ionic salt at a concentration sufficient to create a hostile biophysical environment, the hostile biophysical environment causing the substance to migrate from the delivery vehicle to the selected area of the skin where hair growth is desired, where the substance is absorbed by the selected area of the skin,

wherein said delivery vehicle comprises, by weight water (20%-80%), mineral oil (3%-18%), glyceryl stearate (0.5%-12%), squalene (0.2%-12%), cetyl alcohol (0.1%-11%), propylene glycol stearate (0.1%-11%), wheat germ oil (0.1%-6%), glyceryl stearate (0.1%-6%), isopropyl myristate (0.1%-6%), stearyl stearate (0.1%-6%), polysorbate 60 (0.1%-5%),

propylene glycol (0.05%-5%), tocopherol acetate (0.05%-5%), collagen (0.05%-5%), sorbitan stearate (0.05%-5%), vitamin A&D (0.02%-4%), triethanolamine (0.01%-5%), methylparaben (0.01%-4%), aloe vera extract (0.01%-4%), imidazolidinyl urea (0.01%-4%), propylparaben (0.01%-4%), bha (0.01%-4%), L-arginine hydrochloride (0.25% to 25%), sodium chloride (0.25% to 25%), and magnesium chloride (0.25% to 25%).

57. (Previously Presented) The method of claim 56 wherein the delivery vehicle further comprises choline chloride (0.25%-25% by weight).
58. (Previously Presented) The method of claim 56 wherein the delivery vehicle further comprises L-arginine glutamate (0.25%-25% by weight).
59. (Previously Presented) The method of claim 51 wherein a transdermal patch contains the delivery vehicle, and wherein the substance is selected from the group consisting of L-arginine glutamate (0.25% to 25% by weight), L-arginine hydrochloride (0.25% to 25% by weight) and mixtures thereof.
60. (Canceled)
61. (Previously Presented) A method of delivering to skin a substance that is a nitric oxide precursor selected from the group consisting of L-arginine and L-arginine derivatives, the method comprising the step of:
topically applying to the skin a delivery vehicle for the substance, said delivery vehicle comprising the substance at a concentration of 0.25% to 25% by weight, the substance contained within packaging selected from the group consisting of a liposome, an emulsion of collagen, and a collagen peptide, said packaging being at a concentration within the delivery vehicle sufficient to create an hostile biophysical environment, the hostile biophysical environment causing the packaging to migrate from the delivery vehicle to the skin where the substance is released from the packaging and absorbed by tissue.

62. (Previously Presented) The method of claim 61 wherein the delivery vehicle is applied to the penis.
63. (Previously Presented) The method of claim 61 wherein the delivery vehicle is applied to a selected area of skin where hair growth is desired.
64. (Currently Amended) A method comprising the steps of:
selecting a condition from the group consisting of baldness, poor localized bloodflow, leg ulcers, superficial ulcers, ~~bed~~ confinement to bed and erectile dysfunction;
selecting a nitric oxide precursor means;
selecting a means of delivering the substance to skin from the group consisting of topical creams, topical lotions, and topical ointments, the means comprising choline chloride, sodium chloride, and magnesium chloride; and
topically applying, to the skin having the selected condition, the nitric oxide precursor means, wherein the nitric oxide precursor means is 0.25% to 25% by weight of the means of delivering the substance to the skin.
65. (Previously presented) The method of claim 64 further comprising the steps of:
selecting a means of producing a hostile biophysical environment which increases delivery of the nitric oxide precursor means into the skin; and
topically applying the means of producing a hostile biophysical environment to the skin.
66. (Currently Amended) The method of claim 65 wherein the ~~means of producing the hostile biophysical environment is an~~ ionic salt mixture ~~having~~ has a concentration of 0.25% to 25% by weight of the means of delivering the substance to the skin.

67. (Previously Presented) The method of claim 66 wherein the nitric oxide precursor means is selected from the group consisting of D,L-arginine, L-arginine, esters of L-arginine, and salts of L-arginine.
68. (Canceled)
69. (Previously Presented) The method of claim 67 wherein the salts of L-arginine are selected from the group consisting of hydrochloride, glutamate, butyrate, and glycolate.
70. (Previously Presented) The method of increasing localized bloodflow in tissue of claim 33 wherein the effective amount of the substance is 0.25% to 25% by weight of the delivery vehicle.
71. (Cancelled).
72. (Currently Amended) The method of increasing localized bloodflow in tissue of claim ~~74~~ 33, wherein the agent for creating a hostile biophysical environment has a concentration of 0.25% to 25% by volume of the delivery vehicle.
73. (Currently Amended) The method of increasing localized bloodflow in tissue of claim 33, wherein the delivery vehicle further comprises an agent for creating a hostile biophysical environment is selected from the group consisting of a pharmaceutically acceptable acid, a pharmaceutically acceptable base, polylysine, polyglutamine, polyaspartate, and copolymers of charged amino acids.
74. (Previously Presented) The method of treating impotence of claim 42 wherein the effective amount of the substance is 0.25% to 25% by weight of the delivery vehicle.

75. (Previously Presented) The method of treating impotence of claim 42 wherein the agent for creating a hostile biophysical environment is a salt selected from the group consisting of sodium chloride, choline chloride, potassium chloride, lithium chloride, magnesium chloride, and mixtures thereof.
76. (Previously Presented) The method of treating impotence of claim 75 wherein the agent for creating a hostile biophysical environment has a concentration of 0.25% to 25% by volume of the delivery vehicle.
77. (Previously Presented) The method of treating impotence of claim 42 wherein the agent for creating a hostile biophysical environment is selected from the group consisting of a pharmaceutically acceptable acid, a pharmaceutically acceptable base, polylysine, polyglutamine, polyaspartate, and copolymers of charged amino acids.
78. (Previously Presented) The method of promoting hair growth of claim 51 wherein the effective amount of the substance is 0.25% to 25% by weight of the delivery vehicle.
79. (Previously Presented) The method of promoting hair growth of claim 51 wherein the agent for creating a hostile biophysical environment is a salt selected from the group consisting of sodium chloride, choline chloride, potassium chloride, lithium chloride, magnesium chloride, and mixtures thereof.
80. (Previously Presented) The method of promoting hair growth of claim 79 wherein the agent for creating a hostile biophysical environment has a concentration of 0.25% to 25% by volume of the delivery vehicle.
81. (Previously Presented) The method promoting hair growth of claim 51 wherein the agent for creating a hostile biophysical environment is selected from the group consisting of a

pharmaceutically acceptable acid, a pharmaceutically acceptable base, polylysine, polyglutamine, polyaspartate, and copolymers of charged amino acids.